

Non-Final Office Action

Claims 6-9 are pending. No claim is allowed at this time. A pre-Appeal decision to maintain the rejection has been mailed on 3/5/08.

Previous rejection is withdrawn due to an inadvertent typing error.

Summary of this Office Action dated August 12, 2008

1. Continued Examination Under 37 CFR 1.114
2. 35 USC § 103(a) Rejection
3. Response, declaration and the data in Specification
4. Communication

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/3/08 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 6-9 are rejected under 35 U.S.C. 103 (a) as being unpatentable over ISENRING ET al. (United States Patent No. 6407,100), JAUTELAT et al. (US Patent 5,789,430) and present Specification. These references teach the compounds as antimicrobial agents, which embraces Applicant's claimed invention.

ISENRING teaches trifloxystrobin as fungicide. See the entire document especially lines 10-20 in column 1, lines 34-67 in column 6, abstract, and examples.

JAUTELAT teaches prothioconazole and tebuconazoles as microbicides. See the entire document especially example 1 in column 35, lines 27-64 in column 29, lines 1-55 in column 30 and Table 1 in column 14.

Specification discloses that all the compounds used in the combination are known. See lines 1-18 on page 1.

Instant claims differ from the reference in claiming the combination of all three known compounds useful as antimicrobial and antifungal agents.

It would have been obvious to one skilled in the art at the time of invention was made to combine known compounds for the same purpose in expectation to get a better activity. Since all the above cited reference teach the active compounds as claimed it is *prima facie* obvious to combine two or more

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compositions each of which is taught by the prior art to be useful for the same purpose in order to form a new composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 205 USPQ 1069.

The results presented in the specification on page 11 are not synergistic rather it would have been obvious to one skilled in the art to combine the known active compounds in different ratios. The difference in synergistic efficacy 78 and compound of formula 1 (efficacy 67) does not represent synergism. The data presented in Table A on page 11 of the specification is Pyrenophora teres test on barley (now declaration includes two more examples). The synergism as claimed cannot be predicted for the effect on any other phytopathogenic fungi. The Furthermore, the data does not commensurate with the scope of claims.

Further the legally accepted definition of synergism as meaning “the combined action of two or **more agents** * * * that is greater than the sum of the action of one of the agents used alone” is cited in In re *Luvisi et al*, 144 USPQ 646. In re *Lemin et al*, 161 USPQ 288 points out the necessity of presenting data for each component singly at the total rate applied in combination in addition to the fact that each component must be tested individually at the rate at which it appears in combination.

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In present case each component has not been tested individually at the rate at which it appears in combination.

Applicant's specification discloses that all the compounds in claim 6 are known.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks, Declaration and the data in Specification

The data presented in the declaration filed by Dr. Peter Dahmen has been considered. In example 1 the calculated efficacy 67 and found 75 is not synergistic for *Blumeria graminis*. Example 2 appears to be marginal synergistic for *Fusarium culmorum*. It is clear from the data that the ratio of the three compounds as 1:1:1 does not necessarily will act as synergistic on all the fungi. The claimed subject matter is not limited to such a ratio and fungi.

Examiner has considered the data presented in specification on page 11. The application of the compounds (I), (II) and (III) are 100 g/ha and efficacy is 67, 56

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and 22 percent respectively. The data presented in Table A on page 11 of the specification is Pyrenophora teres test on barley. The data presented in the specification is not a side by side comparison. The amounts g/ha is 100 for the compounds (I), (II) and (III) when their individual efficacies have been observed. However, when synergism according to present invention was calculated the amounts were 35+30+35. The ratios as disclosed are 10:8.5:10.

At first the synergism as claimed cannot be predicted for the effect on any other phytopathogenic fungi and ratios of the components. Furthermore, because of each compound appears to be well known in the prior art, it would appear that the combination of the compounds would have been obvious in view of MPEP 2144.06 and See Ex parte Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992).

The data presented in the specification and in the declaration does not commensurate to the scope of claimed subject matter and does not show any synergism.

Applicant is requested to explain in detail the synergism.

See Ex parte Quadranti where it was held that

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“Use of materials in combination, each of which is known to function for intended purpose, is generally held to be prima facie obvious, and in instant case, use of combination of herbicides is so notoriously well known as to be capable of being taken by official notice; generalizations such as Colby formula are not particularly useful in determining whether synergism has been demonstrated, since formula inherently results in expectation of less than additive effect for combination of herbicides, since there is no evidence that such approach is considered valid by significant number of ordinarily skilled workers in relevant area of technology, and since it could be reasonably argued that in most cases, additive or better than additive results could be expected for combination of herbicides.”

“There is no single, appropriate test for determining whether synergism has been demonstrated for chemical combination; rather, facts shown in each case must be analyzed to determine whether chosen method has clearly and convincingly demonstrated existence of synergism or unobvious result”.

“Assuming arguendo that the differences in values presented are statistically significant, there is no evidence that they represent a true, practical advantage. In re Freeman, 474 F.2d 1318, 177 USPQ 139 (CCPA 1973); In re Klosak , 455 F.2d

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1077, 173 USPQ 14 (CCPA 1972); In re D'Ancicco, 439 F.2d 1244, 169 USPQ 303 (CCPA 1971). Also, prescinding from the Colby formula test, which as we have already indicated is at best controversial and in our view probably invalid, there is no evidence that the differences are unexpected. In re Merck, 800 F.2d 1091, 231 USPQ 375 (Fed.Cir. 1986); In re Longi , 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985); In re Freeman, supra” .

“Immediately above, we assumed arguendo that the results presented were statistically significant. There is in fact no basis for actually making such an assumption, however. No measure of statistical significance in terms either of P values or confidence limits has been presented. This is particularly important where the differences in question are fairly small, as they are here. The irregular nature of the increase in effectiveness as doubled amounts of Compound IIIb are added also gives rise to questions concerning the reproduceability of the tests used and, thus, the significance of the results. Although patent application specifications are generally not held to the same high standard as scholarly scientific publications, in which statistical significance measures are presented routinely almost as a sine qua non , where as here, the data in question are relied on as evidence of unobviousness as it effects the ultimate issue under 35 U.S.C. 103,

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statistical analysis would unquestionably enhance the probative value of that evidence”.

See 201 USPQ 193; In re Kollman and Irwin; U.S. Court of Customs and Patent Appeals No.78-624; Decided March 15; 595 F2d 48

It was held that “Appellants point to various examples of data presented in the specification as establishing synergism at other than the 1:1 ratio. This position is not well taken. This data satisfies but part of the criteria set to determine if synergism exists. For instance appellants point to the test in table I employing 4 lbs. of the ether in combination with 2 lbs. of fenac. However there is no testing of the ether at 6 lbs. nor the fenac at 6 lbs., i.e. no testing of the individual components at the total amount of the combination employed.

The legally accepted definition of synergism as meaning “the combined action of two or more agents * * * that is greater than the sum of the action of one of the agents used alone” is cited in In re Luvisi et al, 144 USPQ 646 . In re Lemin et al, 161 USPQ 288 points out the necessity of presenting data for each component singly at the total rate applied in combination in addition to the fact that each component must be tested individually at the rate at which it appears in combination”.

For the reasons cited above applicants arguments are not found persuasive.

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Due to an inadvertent typing error a new office action is being sent in the response filed on 4/3/08.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/

Primary Examiner, Art Unit 1612

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